

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW MEXICO**

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**STATE OF NEW MEXICO, *ex rel.*  
GARY KING, ATTORNEY GENERAL  
OF THE STATE OF NEW MEXICO,**

Plaintiff,

v.

No. CIV 09-0390 BB/DJS

**ASTRAZENECA  
PHARMACEUTICALS LP,  
ASTRAZENECA LP, ASTRAZENECA  
plc, ASTRAZENECA AB, and  
ASTRAZENECA UK LIMITED,**

Defendants.

**MEMORANDUM OPINION**

This matter comes before the Court for consideration of a motion to remand filed by the State (Doc. 11), as well as a motion for stay of proceedings filed by Defendants (Doc. 4). The Court has reviewed the submissions of the parties and the relevant law. Based on this review, the motion for stay will be denied and the motion to remand will be granted.

**Facts**

The State filed a lawsuit in state court concerning Seroquel, an antipsychotic drug manufactured and marketed by Defendants. The complaint alleged, in essence, that Defendants engaged in a deceptive marketing scheme designed to conceal harmful side effects that often accompany the use of Seroquel, and to exaggerate the benefits of Seroquel for treatment of various psychological conditions. According to the complaint, this harmed the State in two major ways: first, the State was required to pay, through its Medicaid program, for Seroquel prescriptions that were both unnecessary and in many cases affirmatively harmful; second, the State has had to pay for medical expenses incurred by Medicaid patients who suffered ill effects

from taking Seroquel. The State also presented claims as *parens patriae* for physical injuries suffered by patients who were prescribed Seroquel. None of the State's claims expressly invoked a federal statute, the federal Constitution, or federal common law. Despite the absence of any federal claims in the complaint, Defendants removed the case to this Court, and the State has filed a motion to remand. The State maintains this Court does not have jurisdiction to hear the case.

### **Discussion**

This Court has original jurisdiction over all civil actions arising under the Constitution, laws, or treaties of the United States. *See Nicodemus v. Union Pac. Corp.*, 440 F.3d 1227, 1232 (10th Cir. 2006). If a complaint contains only state-law causes of action, as does the one in this case, federal-court jurisdiction may still exist if the plaintiff's right to recover under one or more of the claims in the complaint necessarily depends on resolution of a substantial question of federal law. *Id.* The federal issue raised by the state-law claim must be both actually disputed and substantial in order to provide a basis for federal-court jurisdiction. *See id.*, 440 F.3d at 1233. The question in this case, therefore, is whether any of the state-law claims raised by the State in its complaint necessarily require resolution of a disputed and substantial federal question.

The State points out that this Court has already remanded a similar case involving the State and a different pharmaceutical company. *See State of New Mexico v. Ortho-McNeil-Janssen Pharm., Inc.* (CIV 08-779, D. N.M.). According to the State, this case is jurisdictionally identical to the *Ortho-McNeil* case and therefore remand should be granted in this case as well. Defendants disagree, and raise three arguments in support of their position. First, Defendants point out that there is a multi-district litigation panel ("MDL") considering a number of Seroquel cases in the Central District of Florida, and the MDL has issued a conditional transfer order regarding this case. No MDL was in existence for Risperdal cases, which was the pharmaceutical involved in the *Ortho-McNeil* case. Defendants contend this Court should refrain from ruling on the remand motion and instead issue a stay of proceedings, thus allowing the

MDL judge, Judge Conway, to address the remand motion following transfer of the case to her court. In addition to the MDL argument, Defendants contend the Court's decision in *Ortho-McNeil* was wrong and should not be followed. Finally, Defendants maintain they have raised a substantial federal issue in this case that was not argued or addressed in the *Ortho-McNeil* case, and this substantial federal issue gives rise to federal jurisdiction.

**Motion for Stay:** The decision to stay proceedings or refuse to do so is discretionary with the district court. *See Ben Ezra, Weinstein, and Co., Inc. v. America Online Inc.*, 206 F.3d 980, 987 (10th Cir. 2000). Defendants make two main arguments in support of their motion for stay, contending that principles of judicial economy and consistency in decision-making will be served if the stay is entered and the MDL judge decides the remand issue. They argue that the MDL judge is already quite familiar with the legal and factual issues raised in the State's complaint, having presided over the production of millions of pages of documents as well as extensive legal argument. The Court agrees this is true as to the merits of many of the State's claims; the MDL judge would certainly seem to be more familiar than is this Court with issues such as side effects resulting from use of Seroquel, Defendants' testing of its product and subsequent disclosures, and other issues bearing on the State's claims of misrepresentation, sale of an unreasonably dangerous product, etc. However, the merits of the State's claims are not implicated in any way by the motion for remand, and are thus not relevant to the jurisdictional inquiry. What is important, as noted above, is whether any of the State's claims raise a substantial federal issue that must necessarily be decided to resolve the claim. *See Nicodemus, supra*. As to that question, there is no indication this Court is any less familiar with the issues presented than is Judge Conway. Defendants have pointed to no case in which Judge Conway has analyzed a complaint similar to the one in this case to determine whether the state-law claims alleged in the complaint would necessarily require resolution of a substantial question of federal law. This Court, on the other hand, has already done so in the *Ortho-McNeil* case. Therefore, Defendants' judicial-economy and familiarity-with-the-issues arguments are not persuasive.

The Court is similarly not persuaded by Defendants' consistency-in-decision-making argument. In fact, this principle actually augurs in favor of refusing to grant the requested stay. In the *Ortho-McNeil* case, this Court has already remanded a case in which the complaint was substantially similar to the one filed in this case. If the jurisdictional issues in the two cases are indeed the same, a question which is discussed below, consistency would seem to be better served by having the same judge decide both cases. Transfer to the MDL, on the other hand, would give rise to the risk of a remand decision that would be inconsistent with this Court's ruling in *Ortho-McNeil*.

For the above reasons, the Court will exercise its discretion and deny the motion to stay these proceedings.

**Motion to Remand:** The Court's review of the complaint filed by the State in this case indicates it is substantially similar to the complaint filed in *Ortho-McNeil*. The Court must therefore address Defendants' arguments that, first, the decision in *Ortho-McNeil* was wrong; and second, Defendants in this case have raised a substantial federal question that was not present in the *Ortho-McNeil* case.

**a. Whether A Substantial Federal Question Is Presented by State's Claims:**

Defendants contend the Court's characterization of the State's claims in the *Ortho-McNeil* case was erroneous, as according to Defendants the Court wrongly adopted the State's self-serving description of its claims. Defendants insist the State's claims in *Ortho-McNeil*, and necessarily in this case as well, depend on showing that Defendants violated federal law, not state common law or statutory law. According to Defendants, this is because many of the State's claims are premised on its contention that Defendants promoted the use of Seroquel for "off label" uses,<sup>1</sup>

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<sup>1</sup>Off-label uses of pharmaceuticals are uses that have not been approved by the Food and Drug Administration ("FDA"). Such uses are not illegal, but the FDA has by regulation forbidden pharmaceutical companies from promoting them, except in quite limited fashion. See A. Elizabeth Blackwell and James M. Beck, *Drug Manufacturers' First Amendment Right to Advertise and Promote their Products for Off-Label Use: Avoiding a Pyrrhic Victory*, 58 Food &

knowing that simply engaging in such promotion violates federal regulations. In addition, according to Defendants, the other claims raised by the State amount to a challenge to the federal Medicaid regulations that require the State to pay for prescriptions of Seroquel that were intended for off-label uses. In sum, Defendants contend that a court deciding the State's claims will necessarily have to interpret federal regulations and statutes governing both the FDA and the Medicaid program. The Court, however, disagrees that any of these regulations and statutes will necessarily come into play during the litigation of the State's claims. Those claims are based on allegations of fraud, misrepresentation, failure to warn of Seroquel's dangers, negligence, and strict product liability, among other allegations. None of the claims alleges that Defendants are liable simply for promoting off-label uses of Seroquel in violation of federal law.<sup>2</sup> Instead, they allege Defendants are liable because their promotion of the off-label uses concealed relevant information concerning the safety and efficacy of Seroquel. Similarly, the State does not allege that it had no legal duty to pay for Seroquel prescriptions for off-label uses. As the Court discussed in the *Ortho-McNeil* opinion, the State instead claims that physicians were wrongly induced to issue such prescriptions in the first place, because Defendants withheld relevant information and engaged in affirmative misrepresentations. It is simply not necessary to decide anything about the FDA regulations, the FDCA, or the federal Medicaid statute in order to

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Drug L.J. 439, 440-41 (2003).

<sup>2</sup>The Court's review of the complaint indicates there are a few sparse references to promotion of off-label uses that could be construed as not being premised on the falsity or misleading character of that promotion. *See, e.g.*, Complaint, Par. 29, 50, 81. These few references, in a complaint that contains 212 paragraphs, are insufficient to establish that any of the State's claims necessarily depend on proving that Defendants violated FDA regulations by engaging in prohibited off-label promotion. This is especially true since, as the State argues, all doubts are to be resolved in favor of remand when on its face a complaint alleges only state-law claims. *See Central Iowa Power Co-op. v. Midwest Indep. Transmission Sys. Operator, Inc.*, 561 F.3d 904, 912, 914 (8th Cir. 2009) (court must resolve all doubts about federal jurisdiction in favor of remand; reading complaint as a whole, references to federal law in complaint should be considered important background information rather than attempts to state a basis for a state-law claim).

resolve any of the State's claims, and therefore resolution of those claims cannot "necessarily depend" on resolution of a substantial question of federal law. *See Nicodemus, supra*, 440 F.3d at 1232. Therefore, the complaint in this case, on its face, does not give rise to federal jurisdiction.<sup>3</sup> *Id.*

**b. Whether Defendants' First Amendment Rights Give Rise to Federal Jurisdiction:**

Defendants argue the State's complaint unavoidably raises a First Amendment issue that was not discussed in the *Ortho-McNeil* case. Defendants maintain this issue is a substantial federal question that will necessarily have to be decided in the course of resolving the State's claims. Defendants' argument proceeds as follows: (1) the State's claims are directed at off-label uses for Seroquel rather than FDA-approved uses; (2) as noted above, the FDA does not allow pharmaceutical companies to promote off-label uses for prescription medicines through means such as advertising, even if the statements made during such promotion are truthful; (3) at least some of the State's claims are premised on Defendants' alleged promotion of Seroquel for off-label uses in violation of the FDA's rules and regulations; (4) however, Defendants have a First Amendment right to engage in commercial speech concerning their product; and (5) therefore, the extent of that First Amendment right will have to be decided before the State can prevail on its unlawful-promotion claims.

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<sup>3</sup>The Court notes that only one district court that has considered the question appears to have agreed with Defendants' arguments as to the federal nature of the State's claims, while many other district court opinions are in accordance with the Court's characterization of those claims. *See, e.g., Arkansas v. Astrazeneca Pharm., LP*, 2008 WL 3992746 (E.D. Ark. 2008); *Pennsylvania v. Eli Lilly & Company, Inc.*, 511 F.Supp.2d 576 (E.D. Pa.2007); *Utah v. Eli Lilly and Co.*, 509 F.Supp.2d 1016, 1022 (D. Utah 2007); *South Carolina v. Janssen Pharm., Inc.*, 2007 WL 2022173 (D. S.C. 2007); *Alaska v. Eli Lilly & Co.*, 2006 WL 2168831 (D. Alaska 2006); *contra, e.g., West Virginia v. Eli Lilly & Co.*, 476 F.Supp.2d 230, 232 (E.D. N.Y. 2007). While the views of Judge Weinstein in the Eastern District of New York are eminently defensible on policy grounds, the Court simply cannot find a federal question presented in more than a tangential manner, or as background information, in the State's complaint.

The Court agrees that the First Amendment question discussed by Defendants is a significant issue of federal law. The Court does not agree, however, that this question will necessarily have to be decided in order to resolve any of the State's claims in this lawsuit. As discussed above, none of the State's claims is based solely or even primarily on Defendants' alleged promotion of off-label uses for Seroquel in violation of federal law. Instead, the State's claims are premised on Defendants' alleged misrepresentations and failures to disclose necessary information during their claimed promotion of off-label uses. While commercial speech is entitled to some degree of protection under the Constitution, it is black-letter law that misleading commercial speech is not protected by the First Amendment. *See Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 367 (2002); *Revo v. Disciplinary Bd. of the Supreme Court for the State of New Mexico*, 106 F.3d 929, 932 (10th Cir. 1997). Therefore, to the extent the State can prove its allegations that Defendants engaged in misleading activities during their alleged promotion of the off-label uses for Seroquel, Defendants' First Amendment rights will be irrelevant to the State's claims. Since it will not be necessary to address Defendants' First Amendment rights in order to resolve any of the State's claims, those rights do not present a substantial federal question that gives rise to federal jurisdiction in this case.

### **Conclusion**

The Court has a great deal of sympathy for Defendants' arguments that transferring this case to the MDL court, and allowing the parties to litigate the merits of the State's claims in that court, would be the preferable outcome as far as judicial economy is concerned. As Defendants point out, an enormous amount of discovery has already been performed in the MDL cases, and Judge Conway is familiar with the factual and legal background surrounding Seroquel, including its uses and side effects and Defendants' conduct in marketing it. However, the State has chosen to raise only state-law claims in this case, and these claims do not necessarily implicate a substantial federal question. Therefore, there is no federal jurisdiction over the State's lawsuit and the case must be remanded to the state court from which it was removed. It is to be hoped

that the parties and the state court will not be forced to re-invent the wheel but will be able to utilize much of the work that has already been performed in the MDL cases.

Dated this 16<sup>th</sup> day of July, 2009.

A handwritten signature in black ink, reading "Bruce D. Black". The signature is written in a cursive style with a large, stylized "B" and "B". To the right of the signature is a horizontal line.

BRUCE D. BLACK  
United States District Judge